

REMARKS

Amendments to the Specification

Table 2, missing the definition for the gene PNKP on p. 60, line 32 (the 31st gene in the table) is herein amended to include the definition "Polynucleotide kinase 3' phosphatase."

Applicants respectfully submit that a person of ordinary skill in the art would understand that PNKP is the gene for polynucleotide kinase 3' phosphatase as this is a very common gene, well-known in the art. For this reason, Applicants respectfully submit that no new matter has been introduced by this amendment.

Amendments to the Claims

No new matter has been introduced by these amendments. Support in the application for new claims 187-205 are as follows:

Claim 187

Support for a profile data set is found in the application in original claim 156 and on page 10, line 8 et seq., both of which sections refer to a profile data set, and not specifically a baseline profile data set. Also, p. 28, lines 9-18 state that "The profile data set ... *may* serve as a baseline profile data set ..." and further state that "The resultant calibrated data sets may then be stored as a record in a data base or library (Figure 6) ... and optionally the first profile data set although the first profile data set would normally become incorporated into a baseline profile data set..." (emphasis added). Applicants respectfully submit that such language, when read by a reasonable person of ordinary skill, would be understood to mean that the first profile data set *may* be a baseline profile data set, but is not *required* to be one, and may be stored as a profile data set in its own right.

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Additional support for claim 187 is found in the application on p. 17, line 20 wherein the definition of "panel" is "A set of genes including at least two constituents"; p. 11, lines 9-10 ("the panel may include at least four constituents selected from any one of Tables 1 through 7); and original claim 156, which requires a plurality of members in the data set. See also p. 23, lines 4-5 ("selected panels ... as small as 6, 5, 4, 3, or 2 genes."

Support for the at least 3% coefficient of variation is found in the application on p. 23, lines 6-26. This entire section talks about reproducibility in samples that are repeatedly tested (see, e.g., lines 8-9) and average coefficients of variation for both intra-assay variability and inter-assay variability, described as less than 1% and 2%, respectively (id., lines 12-20). The discussion culminates with the statement that statistical outlier data points are eliminated, and that a data point is determined to be an outlier if it differs by more than 3% relative to the average of all (four) values for a given quadruplicate test. Applicants respectfully submit that given that the intra-assay coefficient of variation for assays done in quadruplicate is less than 1%, and that the inter-assay coefficient of variation for assays done in triplicate is less than 2%, and that statistical outliers for results are eliminated if they differ by greater than 3% of the average of the four measurements, a person of ordinary skill in the art would understand that the coefficient of variation is less than 3%, the cut-off number for determination of statistical outliers.

Support for claims 188-189 is found in the application on p. 23, lines 13-16.

Support for claims 190-191 is found in the application on p. 17, lines 10-12.

Support for claim 192 is found in the application on p. 21, lines 33 to p. 22, l. 3.

Support for claim 193 is found in the application on p. 17, lines 7-12.

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Support for claim 194 is found in the application on p. 21, lines 33 to p. 22, l. 3.

Support for claim 195 is found in the application Title on p. 1, and in the Technical Field, p. 1, lines 12-14. Additional support for characterizing a biological condition is found in the application on p. 40, lines 15-17.

Support for claims 196 -202 is found in the application on p. 11, lines 9-10 and in Tables 1 through 7.

Support for claim 203 is found on page 22. The section on page 22 titled "Selected Panels" (specifically lines 5-17) discusses how to select constituents for a panel that "directly or indirectly vary with a particular biological condition" stating that "... a selected panel is not necessarily selected according to an expected profile of gene expression in cells that directly respond to a biological effect. For example, gene expression associated with liver metabolism may be analyzed in a blood sample."

Support for claims 204-205 is found in the application on p. 28, lines 14-17.

In light of the above arguments, Applicants respectfully submit that there is support in the specification for all the limitations in new claims 187-205 and that no new matter has been added.

In summary, the claims, as amended, have support in the specification and do not contain new matter. Further, for the reasons stated in Response B and Supplement to Response B, the claims are enabled for someone of ordinary skill in the art and the specification, as written, does not require undue experimentation to practice the invention.

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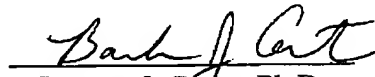
CONCLUSION

For the reasons set forth above, it is submitted that all pending claims are in condition for allowance. Reconsideration of the claims and a notice of allowance are therefore requested.

Applicants do not believe that an extension of time is required; however, this conditional petition for an extension of time is being made in the event that the need for an extension has been overlooked. Please pay any fees required for the timely consideration of this application from deposit account number 19-4972. The Examiner is requested to telephone the undersigned if any matters remain outstanding so that they may be resolved expeditiously.

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Respectfully submitted,


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